APR - 1 2004

stryker
INSTRUMENTS

4100 East Milham Avenue
Kalamazoo, MI 49001
Phone (269) 323-7700
(800) 253-3210

K032406

Device Name:

Trade Name:	Stryker RF Electrodes and Cannulae
Common Name:	Electrosurgical electrode and cannulae
Classification Name:	Probe, Radiofrequency Lesion : 21 CFR 882.4725, GXI

Device Sponsor:

Manufacturer:	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001 Registration No.: 1811755

Regulatory Class: Class II

Summary of Safety and Effectiveness:

The Stryker RF Electrodes and Cannulae, in combination with the Stryker RF Generator, are intended for coagulation of soft tissues in orthopedic, arthroscopic, spinal, and neurosurgical applications.

They are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the spinal cord, peripheral nerves, and nerve roots for the relief of pain. Examples include, but are not limited to, Facette Denervation, Percutaneous Chordotomy/Dorsal Root Entry Zone (DREZ) Lesion, Trigeminus Neuralgia, Pheripheral Neuralgia, and Rhizotomy.

The Stryker RF Electrodes and Cannulae are equivalent in intended use, safety, and effectiveness to existing devices being marketed by Stryker Instruments.

The Stryker RF Electrodes and Cannulae do not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker RF Electrodes and Cannulae are substantially equivalent to these existing devices.

By: Nicole Petty
Nicole Petty
Associate Manager, Regulatory Affairs

Dated: 1-20-04

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Nicole Petty, RAC
Associate Manager, Regulatory Affairs
Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Re: K032406
Trade/Device Name: Stryker RF Electrodes and Cannulae
Regulation Number: 21 CFR 882.4725, 882.4400
Regulation Name: Radiofrequency lesion probe; Radiofrequency lesion generator
Regulatory Class: II
Product Code: GXI, GXD
Dated: January 20, 2004
Received: January 21, 2004

Dear Ms. Petty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K032406

Device Name: Stryker RF Electrodes and Cannulae

Indications For Use:

The Stryker RF Electrodes and Cannulae, in combination with the Stryker RF Generator, are intended for coagulation of soft tissues in orthopedic, arthroscopic, spinal, and neurosurgical applications.

They are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the spinal cord, peripheral nerves, and nerve roots for the relief of pain. Examples include, but are not limited to, Facette Denervation, Percutaneous Chordotomy/Dorsal Root Entry Zone (DREZ) Lesion, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The- Counter Use

(Per 21 CFR 801.109)

Miriam C. Provost (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K032406